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EXAMINER
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KAM, CHIH MIN

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/11/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/645,835

Applicant(s)

KEONING ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 25-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Status of the Claims***

1. Claims 25-37 are pending.

Applicants' amendment and response filed on September 26, 2001 (Paper No. 9) has been entered and fully considered. Claims 1-8 have been canceled.

***Rejection Withdrawn***

***Informalities***

2. The previous objection to the disclosure is withdrawn in view of applicants' corrections made in the specification.

***Claim Rejections - 35 USC § 112***

3. The previous rejection of claims 1-8, under 35 U.S.C.112, second paragraph, is withdrawn in view of applicants' cancellation of the claim.

***Claim Rejections - 35 USC § 102***

4. The previous rejection of claims 1-8, under 35 U.S.C.102(a), is withdrawn in view of applicants' cancellation of the claim.

***Claim Rejections - 35 USC § 103***

5. The previous rejection of claims 1-8, under 35 U.S.C.103(a), is withdrawn in view of applicants' cancellation of the claim.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 25-35 are rejected under 35 U.S.C. 112, second paragraph as being indefinite because of the use of the term "comprising a polypeptide whose amino acid sequence is at least 75% identical to the sequence of SEQ ID NO: 4", "said polypeptide is at least 90% identical to the sequence of SEQ ID NO: 4", "said polypeptide is at least 95% identical to the sequence of SEQ ID NO: 4", "comprising a polypeptide whose amino acid sequence is at least 75% identical to a sequence selected from the group consisting of SEQ ID NO: 2 and 4", "comprising a polypeptide whose amino acid sequence is at least 75% identical to SEQ ID NO: 6", "comprising an amino acid sequence at least 75% identical to a sequence selected from the group consisting of SEQ ID NO: 2, 4 and 6", "said polypeptide is at least 90% identical to the sequence selected from the group consisting of SEQ ID NO: 2, 4 and 6", or "said polypeptide is at least 95% identical to the sequence selected from the group consisting of SEQ ID NO: 2, 4 and 6". The term described above renders the claim indefinite, it is unclear what polypeptide is intended, especially regarding where the conserved amino acid residues are in the sequence and whether the polypeptide with 75% identity and conservative substitution in the sequence has the activity of the polypeptide which is 100% identical to SEQ ID NO: 2, 4 or 6. Claims 26, 27, 29, 30, 32, 34 and 35 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend. Claims 25 and claims dependent thereto: Does % identity differ by conservative amino acid substitution or does the protein/peptide only have conservative substitutions? It is also unclear as to whether or not the identical residues are or are not contiguous regarding the 75%, 90%, 95% and 25% sequence identity to the parent sequence (see, e.g., claims 25-27 and 33).

In response, applicants amend the claim to include conservative amino acid substitutions in the sequence having 75% identity to the parent sequence. However, it is not apparent what are the amino acid sequences of these peptides since the identities of the amino acid residues with the substitutions and their locations are not indicated.

7. Claim 33 is indefinite, is there a sequence for Sp36 against which comparison can be made?

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 31 and 32 are rejected under 35 U.S.C. 102(a) as being anticipated by Spellerberg *et al.* (Infection and Immunity 67, 871-868 (1999)).

Spellerberg *et al.* teach a putative lipoprotein from *Streptococcus agalactiae*, Lmb which exhibits significant homology to streptococcal protein LraI family mediates attachment of *Streptococcus agalactiae* to human laminin and has a peptide sequence of 822 amino acid residues (pages 871, 874-876, Fig. 1). Lmb which has 99.9% sequence homology to SEQ ID NO: 6, absent evidence to the contrary, is expected to react with an anti-pneumococcal Sp36 antibody because the chemical property is inherent in the compound.

In response, applicants amend the claim to include the limitation "wherein said polypeptide reacts with an anti-pneumococcal Sp36 antibody" in claim 31. However, the peptide taught by Spellerberg *et al.* still meets the criteria of claims 31 and 32 because the peptide having

the structure of 99.9% sequence homology to SEQ ID NO: 6 would have the chemical property of SEQ ID NO: 6.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 31, 32 and 37 ~~are~~ rejected under 35 U.S.C. 103(a) as being unpatentable over Spellerberg *et al.* in view of Bentle *et al.* (US 4,694,073).

Spellerberg *et al.* teach a putative lipoprotein from *Streptococcus agalactiae*, Lmb mediates attachment of *Streptococcus agalactiae* to human laminin and has a peptide sequence of 822 amino acid residues (pages 871, 874-876, Fig. 1). The sequence alignment indicates that Lmb has 99.9% sequence homology to SEQ ID NO: 6 and has a Met at N-terminus (versus Val in SEQ ID NO: 6). However, Spellerberg *et al.* fail to disclose the exact sequence of SEQ ID NO: 6. Bentle *et al.* teach conservative substitutions such as substitution of aliphatic residues for one another (Ile, Val, Leu and Met) in Somatotropin do not cause substantial change in the gross chemical properties of a protein (col. 4, line 11-24). At the time of invention was made, it would have been obvious to one of ordinary skill in the art that the protein sequence taught by Spellerberg *et al.* to have modified the proteins of SEQ ID NO: 6 because one of ordinary skill in the art would have been motivated to verify the same activities of the two proteins.

In response, applicants argue that Spellerberg *et al.* only teach the protein reacts with human laminin but do not indicate the protein is immunologically reactive with an authentic



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antiserum, and further indicate the reference does not have each element indicated in the claim to make it obvious. The argument is found not persuasive because the protein taught by Spellerberg *et al.* has only one amino acid difference as compared to SEQ ID NO: 6 and the combined references teach a peptide having the same sequence of SEQ ID NO: 6, which would have the same chemical property as SEQ ID NO:6. Even the chemical property of the protein is not indicated in the reference, the protein would react with an anti-pneumococcal Sp36 antibody because the chemical property is inherent in the compound.

### ***Conclusion***

10. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.  
Patent Examiner

CMK

Christopher S. F. Low

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December 8, 2001

CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
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